

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION**

POZEN INC.

Plaintiff,

v.

SUN PHARMA GLOBAL FZE.

Defendant.

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CIVIL ACTION NO.

PATENT CASE

**ORIGINAL COMPLAINT**

Plaintiff Pozen Inc. (“Pozen”) complains against Sun Pharma Global FZE (“Sun”), and alleges the following:

**The Parties**

1. Pozen is a Delaware corporation, having its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517. Pozen is a specialty pharmaceutical company dedicated to developing therapeutic advancements for diseases with unmet medical needs. Pozen currently specializes in innovative drug products designed to alleviate patient pain and suffering.
2. On information and belief, Sun is a corporation incorporated in the United Arab Emirates with its principal place of business at Office No. 43, Block-Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.
3. On information and belief, Sun is in the business of developing, manufacturing, distributing and selling generic drug products throughout the United States, including for distribution and sale in this district.

**Nature of the Case**

4. This is an action for infringement of United States Patent Nos. 6,060,499 (a true and correct copy is attached hereto as Exhibit A), 6,586,458 (a true and correct copy is attached hereto as Exhibit B). This action is based on the Patent Laws of the United States as found in 35 U.S.C. § 100, *et seq.*

**Jurisdiction and Venue**

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), (d) and 1400(b).
6. This Court has personal jurisdiction over Sun because Sun has systematic and continuous contacts with this jurisdiction.
7. On information and belief, Sun manufactures, sells and distributes generic drug products throughout the United States and specifically in this judicial district.

**Background**

8. On May 9, 2000, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 6,060,499 (the ’499 patent), entitled Anti-migraine Methods and Compositions Using 5-HT Agonists with Long-Acting NSAIDS. The ’499 patent issued to Pozen as the assignee and is currently assigned to Pozen.
9. On July 1, 2003, the PTO issued U.S. Patent No. 6,586,458 (the ’458 patent), entitled Methods of Treating Headaches Using 5-HT Agonists in Combination with Long-Acting NSAIDS. The ’458 patent issued to Pozen as the assignee and is currently assigned to Pozen.
10. On April 15, 2008, the United States Food and Drug Administration (“FDA”) approved Pozen’s new drug application for Treximet™, NDA No. 21-926. Treximet™ is a tablet

for oral administration and contains 85 mg of sumatriptan (present as a succinate) and 500 mg of naproxen sodium.

11. Treximet™ is approved for the acute treatment of migraine attacks with or without aura.
12. Pursuant to 21 U.S.C. § 355(b), Pozen submitted patent information for the '499 and '458 patents for inclusion in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." The FDA thereafter listed the '458 patent in the Orange Book in connection with the Treximet™ NDA.
13. On information and belief, Sun filed papers with the FDA allegedly constituting an abbreviated new drug application under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet™. On information and belief, the FDA assigned Sun's ANDA submission ANDA No. 202803 (hereinafter "Sun's ANDA").
14. On information and belief, the product that is the subject of Sun's ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter referred to as the "Generic Product").
15. On information and belief, Sun intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.
16. On April 15, 2011, Pozen received a letter from counsel for Sun (the "Notice Letter") advising that Sun had submitted ANDA No. 202803 and that its ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV certifications, that in Sun's opinion, '499 and 458 patents are invalid,

unenforceable, and/or will not be infringed by the manufacture, use, sale, or importation of the product that is the subject of the Sun ANDA.

17. The Notice Letter also advised that Sun intends to market the Generic Product before the expiration of the '499 and '458 patents.

#### **Related Case**

18. On October 12-15, 2010, this Court heard a related case in which Pozen presented evidence that Defendants Par Pharmaceuticals, Inc., Alphapharm Pty Ltd. And Dr. Reddy's Laboratories, Inc. similar submission of Abbreviated New Drug applications ("ANDA") to market a generic version of Treximet infringed, *inter alia*, claims of the '499 and '458 patents. *Pozen Inc. v. Par Pharmaceuticals, Inc., et al.*, Case No. 6:08 CV 437.
19. On April 14, 2011, this court issued an order that "Defendant Par Pharmaceutical, Inc. is enjoined from making, using, selling, offering to sell, or importing into the United States products that are the subject of Par's [ANDA] until the issuance of a final decision and order in this case."

#### **Count I – Infringement of the '499 and '458 Patents**

20. Pozen incorporates by reference and repeats the allegations in paragraphs 1-19 above.
21. Defendants' submission of ANDA No. 202803 to the FDA, including the Paragraph IV certification to the '499 and '458 patents contained therein, constitutes infringement of the '499 and '458 patents under 35 U.S.C. § 271(e)(2)(A).
22. Defendants' commercial manufacture, offer for sale, sale, importation or use of the Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of the '499 and '458 patents.

23. Upon information and belief, Defendants were aware of the '499 and '458 patents when they submitted their ANDA.

**Prayer for Relief**

In view of the foregoing, Pozen respectfully requests the following relief:

- A. A judgment that Sun's submission of ANDA No. 202803 constitutes infringement of one or more claims of the '499 patent;
- B. A judgment that Sun's submission of ANDA No. 202803 constitutes infringement of one or more claims of the '458 patent;
- C. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Sun's ANDA shall not be earlier than the expiration date of the '499 patent, including any extensions thereof;
- D. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Sun's ANDA shall not be earlier than the expiration date of the '458 patent, including any extensions thereof;
- E. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Sun, its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Sun or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Generic Product;
- F. Costs and expenses incurred in pursuing this action; and
- G. Any other relief the Court deems just and proper.

Respectfully submitted,

/s/ Stephen M. Hash

Stephen M. Hash

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